



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3389]

Determination That PONDIMIN (Fenfluramine Hydrochloride) Tablets, 20 Milligrams and 60 Milligrams, and PONDEREX (Fenfluramine Hydrochloride) Capsules, 20 Milligrams Were Withdrawn From Sale for Reasons of Safety or Effectiveness.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that PONDIMIN (fenfluramine hydrochloride (HCl)) tablets, 20 milligrams (mg) and 60 mg, and PONDEREX (fenfluramine HCl) capsules, 20 mg, were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for fenfluramine HCl tablets, 20 mg or 60 mg, or fenfluramine HCl capsules, 20 mg.

FOR FURTHER INFORMATION CONTACT: Robin Fastenau, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6236, Silver Spring, MD 20993-0002, 240-402-4510.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure.

ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PONDIMIN (fenfluramine HCl) tablets, 20 mg, and PONDEREX (fenfluramine HCl) capsules, 20 mg, were the subject of NDA 16-618, held by Wyeth Pharmaceuticals, and were initially approved on June 14, 1973. PONDIMIN (fenfluramine HCl) sustained release tablets, 60 mg, was the subject of NDA 16-618, held by Wyeth Pharmaceuticals, and was initially approved in 1982. PONDIMIN and PONDEREX were indicated for treatment of obesity.

In 1997, FDA asked that PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules be withdrawn from the market after receiving new evidence that the products were associated with valvular heart disease (September 15, 1997, FDA Announces Withdrawal Fenfluramine and Dexfenfluramine (Fen-Phen), available on the Internet at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm179871.htm>; see FDA November 1997 Fen-Phen Safety Update Information, available on the Internet at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm072820.htm>). Wyeth Pharmaceuticals subsequently discontinued marketing these products. On October 8, 1998, FDA issued a Notice of Proposed Rulemaking proposing to include certain drug products on a list of drug products that had been withdrawn or removed from the market because such drugs products or components of such drug products had been found to be unsafe or not effective, and which could not be compounded under section 503A of the FD&C Act (63 FR 54082). FDA identified in that notice “all drug products containing fenfluramine hydrochloride.” The notice also noted that fenfluramine HCl tablets, formerly marketed as PONDIMIN tablets, were associated with valvular heart disease, and the manufacturer voluntarily withdrew the drug from the market. This proposed rule was finalized in 64 FR 10944 (March 8, 1999), 21 CFR 216.24.

In the Federal Register of May 5, 2004 (69 FR 25124), FDA issued a notice that it was withdrawing approval of 92 new drug applications and 49 abbreviated new drug applications, including PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules, under section 505(e) of the FD&C Act. Consistent with § 314.161 and its prior rulemaking on compounded drug products under 21 CFR 216.24, FDA has determined that PONDIMIN

(fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules were withdrawn from sale for reasons of safety or effectiveness. This determination is consistent with FDA's prior request and Wyeth Pharmaceutical's withdrawal of PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules from the market for reasons of safety or effectiveness. The Agency previously removed PONDIMIN (fenfluramine HCl) tablets and PONDEREX (fenfluramine HCl) capsules from the list of drug products published in the Orange Book. FDA will not accept or approve any ANDAs that refer to these drug products.

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-24619 Filed: 9/28/2015 08:45 am; Publication Date: 9/29/2015]